

# Innovations in Respirator Design and Fit Testing



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# Background



- Institute of Medicine reports recommended long-term research activities to develop respirators with improved fitting characteristics or respirators that don't need fit testing
- Input to the NIOSH research agenda from a variety of resources
  - Workshop
  - Literature review
  - Final report
- Prioritize the NIOSH research agenda and suggest possible future changes to respirator certification testing procedures and policies
- Half facepiece negative pressure respirators

# Research Goals



- ◉ Advisory Board representing range of stakeholders
- ◉ Plan and hold one-day workshop
- ◉ Identify successful and less successful innovations
- Interview experts for each innovation
- Review written materials (patents, research reports and publications, etc.)
- Prepare final report

# Advisory Board



- Nicole Vars McCullough, 3M Company
- Alan Hack, Los Alamos National Laboratory (retired)
- Jeff Weed, Weed Respiratory Protection Solutions
- Peter Nelson, Silent Power, Inc. and Breathe Safely
- Janice Bradley, International Safety Equipment Association
- Howard Cohen, University of New Haven
- Jeff Birkner, Moldex Metric Inc.
- Bill Borwegen, Service Employees International Union
- Curt Hering, Toronto EMS
- Mark Catlin, Service Employees International Union

# Workshop



- November 6, 2008 – Pittsburgh PA
- 120 participants
- 11 speakers; 13 posters
- 3 breakout sessions
  - New materials and designs for better fit
  - Fit test methods that would ensure long term fit
  - What do we need to know about fit that would lead to better materials, designs or fit tests?
- Presentations and summaries of breakout sessions available on-line at:
  - <http://cpheo.sph.umn.edu/cpheo/mcohs/>

# Innovation

- “Market Pull” – recognition of market needs
- “Technology Push” – advances in technology



Positive Effects of Regulations	Negative Effects of Regulations
Encourage collaboration on research and development	Decrease period of patent protection
Encourage innovation in new technologies or markets	Redirect personnel (participate in regulatory-related activities)
Reduce risk	Delays to marketing (testing and approval)
Limit unpredictable product liability	Additional costs and expertise (may prevent smaller companies from entering the market)

# Innovations



- Surveyed respirator professionals (Advisory Board, AIHA committee, NIOSH researchers)
  - 16 completed surveys
- Selected 4 successful innovations
  - Double flanged facepiece (elastomeric respirators)
  - Flat fold design (filtering facepiece respirators)
  - Ambient aerosol fit test method
  - Head-strap cradle
- Selected 2 less successful innovations
  - Adhesive respirators
  - User seal checks

# Interviews



- 23 interviews
- Interview questions addressed:
  - Incentives for the innovation
  - Costs of research, development and commercialization
  - Effect on respirator use and regulations
  - Effect of regulations on innovation
  - Primary reasons for success (or lack of success)
  - Effect on respirator fit



# Findings



- Technology push and market pull were important to many of the innovation we examined
- Additional drivers also important:
  - Significant levels of funding for research and development
  - New stakeholders and new uses
  - Researchers and research publications
  - Health and safety professionals

# Regulatory Agency Goals



- Emphasis on high levels of product performance to ensure worker protection
- Performance-based approaches to allow for new ideas and designs
- Responsive to changes in technology, materials, designs and uses

# Does Innovation Continue?



- Yes – in companies, universities, government agencies
- Success depends on combination of:
  - Specialized knowledge
  - Preliminary and supporting research
  - Significant financial support
  - Regulatory assistance and flexibility
  - Health and safety & user acceptance

# Research Recommendations



- Additional research would assist designers, manufacturers, professionals, regulators and users:
  - Effectiveness of user seal checks
  - Effectiveness of different filtering facepiece designs
  - Improvements in face seals through use of new technologies and materials
  - Strap designs
  - Trade-off between protection and comfort
  - Methods for constantly checking fit (during wear)

# Recommendations for Other Activities



- Advisory panels representing key stakeholders
- Formal collaborations with government agencies
- Formal assistance to inventors and small businesses
- Advisory committee to conduct regular review of regulations in light of new research
- More interactions between internal and external researchers

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**Opinions are my own and do not  
necessary reflect those of NIOSH**